UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
McALLEN DIVISION

CAYETANO POLANCO	§	
	§	
Plaintiff,	§	
VS.	§	**CIVIL ACTION NO. 7:13-cv-568**
	§	
INNOVATION VENTURES, LLC	§	
dba LIVING ESSENTIALS, LLC	§	
	§	
Defendant	§	

RESPONSE TO MOTION FOR SUMMARY JUDGMENT

COMES NOW, CAYETANO POLANCO, plaintiff, and files this, Plaintiff's Response to Defendant's Motion for Summary Judgment, and respectfully shows the court as follows:

Professor Prosser:

"The *public interest* in human safety *requires* the *maximum* possible *protection* for the ***user*** of the product, and those best able to afford it are the suppliers of the chattel. By placing their goods upon the market, the suppliers represent to the public that they are suitable and safe for use; and by packaging, advertising, and otherwise, they do everything they can to induce that belief …" Prosser, The Fall of the Citadel, 50 Minn. L. Rev. 791, 799 (1966).

The Court should deny defendant's motion for summary judgment in its entirety because Defendant had a legal duty to design a safe product. Whether or not the 5 Hr. Energy Shot caused Mr. Polanco's heart attack (*genuine issue of material fact)* is a fact question for the jury. Plaintiff hereby attaches to this response more than a scintilla of competent evidence to support all of plaintiff's legal claims and genuine issues of material facts exist between the parties.

I. Mr. Polanco's heart attack

On Monday, September 17, 2012, Mr. Cayetano Polanco, a Hispanic, was driving south from West Texas to his home in South Texas. Mr. Polanco had gone to visit family and was driving south for about 9 hours with his significant other, Ms. Irma Anchondo, her brother and her elderly parents. During the trip, Mr. Polanco refueled his vehicle at a convenience store and while paying, he saw a 5 Hr Energy shot bottle placed in front of him by the payment counter and Mr. Polanco, impulsively purchased the energy shot to use in his long car trip. *See attached Exhibit No. 1, Mr. Polanco's deposition excerpt.* Mr. Polanco stopped at the highway rest stop just south of Falfurrias on Highway 281 and switched driving duties with Mr. Angel Mugica, Irma's brother. Seated in the front passenger seat, Mr. Polanco ingested the energy shot, which caused his plaque to rupture, which led to his eventual heart attack. After 15 minutes, Mr. Polanco felt it, as advertised. *See attached Exhibit No. 2, Picture of shot bottle*. He felt anxious, uncomfortable, with a feeling of "hunger" and not right, not himself. He arrived home, went straight to bed, laying down made him feel better and went to sleep.

The next morning, Tuesday, September 18th, he woke up and things were a lot worse. He felt chest pain, sweating, jaw pain, pain radiating down his arm and nauseous. This he felt as a consequence of the plaque rupture clotting and narrowing the blood vessel, consequently reducing blood flow to heart tissue. He laid down in his couch feeling like this for 3 hours. He called Irma to come home from work during lunch so that she could take him to the Hospital. Mr. Polanco was taken to the hospital,

not via ambulance. When he arrived at the Hospital, after the long wait, doctor's attended Mr. Polanco. The initial diagnosis was unstable angina, a form of Acute Coronary Syndrome (ACS), commonly known as a heart attack. Mr. Polanco had chest pain, jaw pain & pain radiating down his arm, all well known physical symptoms of unstable angina, a heart attack.

While hospitalized the first time, lab work was done. Doctors ordered Troponin (cardiac enzyme released only after myocardial injury) levels be tested, the standard way to confirm heart injuries. The lab results evidenced elevated Troponin levels, not once but multiple times, which unequivocally evidenced Myocardial injuries. After a couple of days, Mr. Polanco was released on Thursday, September 20th from the Edinburg Hospital

After arriving home, Mr. Polanco did not feel right. He went to consult a doctor in Progreso, Mexico. Mr. Polanco was recommended to return to an American hospital for further treatment. On Monday, September 24th, Mr. Polanco went back to the emergency room of a hospital, the McAllen Heart Hospital, the second hospitalization. Doctors at such hospital, documented the ACS symptoms, his condition worsened from unstable angina to a myocardial infarction. After further testing confirmed his heart vessel blockage, a balloon pump (literally a balloon placed inside the body which inflates and deflates to assist the heart pumping) had to be used to assist "bridge" Mr. Polanco to his quintuple bypass surgery.

Mr. Polanco was told he may not survive the surgery, he was anesthetized and his chest was cracked, sawed open. Arteries from his leg (leg is now forever numb) had

to be taken from his leg to be used in his heart. Thanks to God, his surgery was successful, his recovery was good. Life will never be the same for him. He has wires inside his chest (used to wire together his chest cavity), which are painful and uncomfortable. The pain prevents him from simple but important for his quality of life, signs of affection, like being able to hug his grandkids and those he loves. It has also taken sexual enjoyment away from his life. Not only does the heart pump harder and that is scary, but also the wires prevent physical contact. While at the hospital, doctors correlated the energy shot ingested with his heart attack and documented it within the medical records.

Mr. Polanco is an individual who was undiagnosed and had unknown heart disease. Three years prior, August 2009, a cardiology stress test and EKG were performed and the results were all normal. Mr. Polanco did have two (2) risk factors for heart disease. He used to smoke and had a history of elevated cholesterol. Regarding the cholesterol, Mr. Polanco had high levels detected during 2009 & 2010, however, after medication treatment, his cholesterol levels were significantly improved by February 2011 and completely normal by July 2011. *See attached Exhibit No. 3, Dr. Wong's Deposition Excerpts.* July 2011 is at least 14 months prior to September 2012, the date of heart attack. So while Mr. Polanco had a history of high cholesterol, his levels were completely normal since July 2011.

After a long and meaningful consideration, Mr. Polanco courageously decided to sue the defendant, taking on a billion dollar company, seeking equitable compensation for his injuries and damages caused by the ingestion of defendant's product. Defendant

has filed a motion for summary judgment on all claims, basically asserting that no evidence exists to prove up plaintiff's legal claims. This response is filed in opposition to defendant's motion, all attached exhibits are hereby incorporated, and is filed in support of plaintiff's request for the Court to deny defendant's motion in its entirety. We ask the court to allow Mr. Polanco an opportunity to prove to a jury with competent evidence that the 5 Hr Energy shot caused his heart attack, and that he is entitled to a judgment of liability on all of plaintiff's legal claims.

II. Dr. Wong

Defendant mischaracterizes Dr. Wong's testimony and Mr. Polanco's health condition. First, defendant leads the court to believe that Mr. Polanco's cholesterol levels were high at the time of the energy consumption and such is not correct. Mr. Polanco's medication had worked, it had evidently reduced his cholesterol levels and consequently his health was improving at the time he ingested the energy shot. *See Exhibit 3.*

Defendant also informs the court that Mr. Polanco complained of chest pain during 2009 to Dr. Wong. However, defendant keeps from the court that Dr. Wong referred Mr. Polanco to a cardiologist, Dr. Yarra, who performed a stress test and an EKG and the results were all normal. *See attached Exhibit 4, Dr. Yarra deposition excerpts.*

III. SUMMARY JUDGMENT LEGAL STANDARD

The standards for reviewing a motion for summary judgment are well established: (1) the *movant* for summary judgment has the *burden* of showing that no

genuine issue of material fact exists and that it is entitled to judgment as a matter of law; (2) in deciding whether there is a disputed material fact issue precluding summary judgment, evidence favorable to the non-movant will be taken as true; and (3) every reasonable inference must be indulged in favor of the non-movant and any doubts must be resolved in its favor. *Nixon v. Mr. Prop. Mgmt. Co.*, 690 S.W.2d 546, 548-49 (Tex. 1985). *Matsushita Elec. Indus. Co. v. Zenith Radio,* 475 U.S. 574, 587, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986)

The issue for the court is *whether* the movant met its summary judgment *burden* by establishing that *no genuine issue of material fact exists* and that the movant is *entitled* to judgment as a matter of law. *Only* if movant met its burden, *then* the burden *shifts* to non-movant to produce competent controverting issues of a material fact in order to defeat movant's motion for summary judgment. *Mann Frankfort Stein & Lipp Advisors, Inc. v. Fielding*, 289 S.W.3d 844, 848 (Tex. 2009). *If* the moving party *fails* to meet its initial burden, summary judgment *must be* denied and the court *need not consider* the nonmoving party's evidence. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 159-60 (1970).

Summary judgment shall be rendered when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); *Ragas v. Tennessee Gas Pipeline Co.,* 136 F.3d 455, 458 (5th Cir. 1998). To establish the existence of a factual dispute, the

opposing party need not establish a material issue of fact conclusively in its favor. It is sufficient that the claimed factual dispute be shown to require a jury or judge to resolve the parties' *differing versions of the truth* at trial. *Phillips v. C.R. Bard, Inc., 2014 U.S. Dist. LEXIS 174506, decided December 16, 2014.* At the summary judgment stage, a court's function is not to weigh the evidence and determine the truth, but to determine whether there is a genuine issue for trial. See *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 249 (1986).

IV. DESIGN DEFECT

Whether a defect exists rests on causation.

Defendant stated in its motion for summary judgment that to recover for a product liability claim alleging design defect Mr. Polanco must prove that (1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which Mr. Polanco seeks recovery.

One of defendant's main arguments is that Mr. Polanco does not have expert testimony to prove up his legal claims. Mr. Polanco has tendered Dr. Changlani's testimony to prove up causation. Plaintiff is not required to produce experts to prove up *all* of the elements of his legal claims. Causation is key to plaintiff's claims and Dr. Changlani's testimony, the medical records and the treating physicians testimony are a lot more than a scintilla of evidence of causation in this case.

-- UNREASONABLY DANGEROUS

The first prong requires Mr. Polanco to produce more than a scintilla of evidence to substantiate his allegations that he ingested a 5 Hr Energy shot (2 oz. shot of 200 mg

of caffeine) that was defectively designed so as to render the product unreasonably dangerous. Dr. Changlani identified the "defect" both in his report and at his deposition, he identified the high levels of caffeine as the culprit for Mr. Polanco's heart attack. *See Exhibit No. 7, Dr. Changlani Expert Report,* and see below *Dr. Changlani deposition excerpt* at page 351, lines 12-15.

> **Defense Counsel**: "And by the way you have not identified a defect with 5-hour ENERGY; is that correct?
> **Dr. Changlani**: "I just know that contains 200 milligrams of caffeine."

As evidence that Mr. Polanco ingested the energy shot, we have Mr. Polanco's and Ms. Irma Anchondo's deposition testimony. *See attached Exhibit No. 6, Mr. Polanco's Deposition excerpts.*

As for evidence that the shot is defectively designed as to render it unreasonably dangerous, we have the known effects of caffeine on the human body, the evidence of the heart attack (ACS) suffered by Mr. Polanco, the evidence linking the injuries to the shot ingestion and the evidence of causation testified by Dr. Changlani. *See attached Exhibit 5, Medical records & Exhibit No. 8, Troponin lab reports.* The medical records evidence chest pain and the physical manifestations of Unstable Angina (ACS) also known as a heart attack. The Troponin lab results evidence the high levels evidencing myocardial injury and the trending down, evidence the "wash out" phase after an episode of a heart attack. The Troponin levels further evidence the time of the plaque rupture, and dated it back to the same time that Mr. Polanco started with his symptoms. *See attached Exhibit No. 9, Dr. Changlani deposition excerpts*. Therefore, two independent sources (Troponin levels, which are objective lab reports & onset of symptoms-

subjective, Polanco testimony) coincide with being triggered, caused, by the ingestion of the energy shot.

As further evidence that the shot was defectively designed, please refer to defendant's numerous consumer reports of adverse events after product's ingestion which allegedly led to heart attacks and heart problems. *See attached Exhibit No. 10, FDA Adverse events, Advisory public report.* While the FDA report does not constitute evidence of causation, it does constitute evidence that the defendant had been told by its customers that the product might contain a defect, that is, the continued emergency hospital interventions to treat many of defendant's customers after the ingestion of its energy shot. The fact that so many, many people complained to the defendant of heart injuries after consumption of their shot, should have led a reasonable, prudent seller to investigate and determine whether or not a defect exists for a certain group of people, those at an increased risk of hear injuries.

The shot is not designed with the purpose of giving people heart attacks. If Mr. Polanco can establish that the shot caused him to suffer a heart attack, then surely the energy shot failed to perform in the manner reasonably to be expected "in light of its nature and intended function. The shot's "defect" is the lack of fitness as evidenced by the malfunction itself rather than some specific dereliction by the manufacturer.

Defendant states in its motion that "to determine whether a product is "unreasonably dangerous," Texas courts adopt a "risk- utility analysis," which requires courts to consider the following factors: "(1) the utility of the product to the user and to

the public as a whole weighed against the gravity and likelihood of injury from its use; (2) the availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive; (3) the manufacturer's ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs; (4) the user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and (5) the expectations of the ordinary customer."

In the case at bar, factor 2 is key and supports the plaintiff's case, that is, the availability of many, many substitute products, which meet the same need, that are not unsafe and are not unreasonably expensive. *See Exhibit No. 11, Alternative safe products.* All of the products depicted contain high amounts of caffeine, however, none have as much caffeine as the 5 Hr Energy shot and all of them deliver caffeine in significantly larger containers, diluting the caffeine in significantly larger volume of liquid. The rate of ingestion is significantly slower since it takes customers a significant more amount of time to ingest the caffeine. *See Exhibit No. 12, pictures of alternative products showing caffeine amounts and volume (ounces) of liquid per safer alternative products.*

Factor 3 is also key and supports the plaintiff's case, because it is quite easy for the manufacturer to eliminate the unsafe character without impairing the product's usefulness or significantly increasing the costs. Either by using a larger container or using the same container with half the caffeine, a single dose. The defendant very easily could have used a 4 oz bottle or use the same 2 oz bottle, with half the caffeine. *See*

attached Exhibit 14, video (3:35 min) of 5 Hr Energy owner explaining product origination and marketing strategies, TieCon 2013. The defendant chose to use a 2 oz bottle in order to avoid competition and give itself a significant competitive advantage over its "energy products" competitors. The safety of the product nor the well being of its customers, including Mr. Polanco, were not a significant factor considered by the defendant when it chose the bottle size used to *push* its high caffeine energy shot, peddling their stuff via trunk slammers.

The fourth (4) factor is also important and supports the plaintiff's case, because there is no user's anticipated awareness of the dangers inherent in the product and defendant does not market the danger. *See attached Exhibit No. 13, Mr. Polanco deposition excerpts, Exhibit No. 15, 5 Hr. Energy official statement, Exhibit No. 16, bottle label and Exhibit No. 17, Marketed for Long trips.* Defendant denies the danger and further prevents the public from widespread knowledge of the risks associated with its product. For a certain group of people, people with heart disease (like Mr. Polanco), ingesting the energy shot is unreasonably dangerous. *See Exhibit No. 7, Expert Report, Exhibit No. 18 - Dr. Golam Deposition Excerpts, Exhibit No. 19, Dr. Wong, Exhibit No. 20, Dr. Yarra, Exhibit No. 21, FDA Caffeine Literature and Exhibit No. 22, CBS News video interview.*

Mr. Polanco's extent of knowledge, a fact question, regarding the risks surrounding the ingestion of 5 Hr. Energy shot also precludes summary judgment on Mr. Polanco's design defect claim, whether sounding in strict products liability or negligence.

Last, customers are led to believe that the energy shot is safe to consume, since it is being sold at a local convenient store, next to the candy and other chocolate. *See attached Exhibit No. 23, Mr. Polanco deposition excerpts.* The product's ***intended use*** as ***marketed*** is to be used for ***long trips***, Mr. Polanco used in such a manner, the customer's expectations are that it was safe for use in long drive trips. *See attached Exhibit No. 17.* The product is sold in practically every convenient store, every Walmart, every Walgreen's, every CVS pharmacy, the product is sold everywhere. *See attached Exhibit No. 24, various receipts.* Mass marketing leads reasonable people to believe the product is safe for all. It is not safe for all.

-- SAFER ALTERNATIVES EXIST.

The second prong requires the plaintiff to produce more than a scintilla of evidence than a safer alternative design existed. For evidence of this, see attached *Exhibit No. 12, Safer Alternative Products, Pictures of various consumer products, which constitute pictures of the actual trial exhibits.* The safer alternative products all contain less amounts of caffeine in a diluted manner, meaning all of the safer alternative products consist of much more volume of liquid per comparable amounts of caffeine. All other products slow down the rate of ingestion by changing the manner of ingestion (the more liquid the slower the rate of ingestion).

Alternative designs, *Exhibit 12,* substantially reduce the risk of injury and are both economically and technologically feasible. Whether it be a Red Bull © Energy Drink, a Monster © drink, a RockStar © drink or a Starbucks © coffee, all of those comparable products are alternative designs that are safer than the 5 Hr shot because of

the way they are consumed, larger amounts of liquid and less caffeine. The large volume of liquid significantly reduce the risk of personal injury without substantially impairing the product's utility. *See attached Exhibit No. 25.* All other products provided also provide a boost of energy, however, it is done in a safer manner without impairing the product's ability to boost energy.

The safer alternative are also economically and technologically feasible. There is nothing cost prohibitive about using a larger container instead of 2 oz bottle. Many consumer drinks are sold in 12 oz, 8 oz or 20 oz capacity. *See Exhibit No. 12.* It was also technologically feasible for defendant to sell its product in a larger container. Alternatively, the same 2 oz bottle could have been used with a significant decrease in the amount of caffeine per 2 oz bottle. The size of the bottle was determined by defendant's intent to place its product at the cash register aisle instead of being placed next to the energy drink competition, at the drink aisle. *See attached Exhibit 14.*

-- PRODUCING CAUSE

The third prong requires that the defect be a producing cause of the injury for which plaintiff seeks recovery. In this case, Mr. Polanco is seeking to establish liability on defendant and then be entitled to compensation for his injuries, to include the heart attack (Acute Coronary Syndrome "ACS"), the open-heart surgery and the life changing consequences felt & lived thereafter.

Given that the causation burden of proof at the summary judgment phase is only "more than a scintilla of evidence," which is significantly lower than the burden

established by Rule 702, and since there is a pending *Daubert* motion seeking to strike Dr. Changlani's testimony, it would seem that the court's *Daubert* ruling would control, apply and determine the issue of causation for purposes of summary judgment; therefore, Mr. Polanco requests the court to not apply *Daubert* at the summary judgment phase and instead wait until a trial setting, which provides the best operating environment for the triage which *Daubert* demands.

There can be more than one proximate cause of an event. See *Travis v. City of Mesquite,* 830 S.W. 2d 94, 98 (Tex. 1995). Under Texas law a plaintiff does not need direct evidence to satisfy causation. *Tompkins v. Cyr*, 202 F.3d 770, 782 (5th Cir. 2000). Circumstantial evidence and reasonable inferences therefrom are a sufficient basis for a finding of causation. *Texas Dept. of Transportation v. Olson*, 980 S.W.2d 890, 893 (Tex. App.--Fort Worth 1998), citing *Havner v. E-Z Mart Stores, Inc.*, 825 S.W. 2d 456, 459 (Tex. 1992). Establishing causation requires facts sufficient for the fact-finder reasonably to infer that the defendants' acts were a substantial factor in bringing about the injury.

Whether something constitutes a proximate cause of an event is a question of fact particularly within the province of a jury. See *El Chico Corp. v. Poole*, 732 S.W. 2d 306, 314 (Tex. 1987); *Strakos v. Gehring*, 360 S.W. 2d 787, 792 (Tex. 1962). It can be a question of law for the court where there is *no material dispute about the evidence* and the circumstances are such that reasonable minds could not come to a different conclusion.

In this case, the substantial factor theory is supported by the attached evidence: the deposition testimony of Mr. Polanco, the medical records and the attached deposition excerpts of Dr. Changlani. *See attached Exhibit No. 7, Expert Report and all*

Exhibits of Dr. Changlani deposition excerpts attached to this Response and all of the Exhibits attached to the Response in Opposition to Exclude Dr. Changlani. Dr. Changlani's report and deposition testimony evidence that in his opinion, causation of the plaque rupture is multi-factorial. He list other possible causes, such list includes that (1) it could have been spontaneous (not triggered by a specific factor), or (2) the stress of the 10 hour drive, or (3) the 5 Hr. Energy shot consumption, or (4) other caffeine products ingested (coca cola drinks). Contrary to defendant's assertions, Dr. Changlani does rule them out when he reaches his conclusion, that it was the energy shot that triggered the plaque rupture. *See attached Exhibit No. 7, Expert Report & Exhibit No. 26, Dr. Changlani rules out other factors.* He further states, than in his opinion, the energy drink was a substantial cause because, more likely than not, was the trigger for his heart attack. *See attached Exhibit 7, Expert report.*

III. MARKETING DEFECT

Whether there was a defect rests on causation.

The existence of a duty to warn of dangers or instruct as to the proper use of a product is a question of law. **The adequacy of a warning, however, is a question of fact for the jury.** *Wright v. Ford*, 2005 U.S. Dist. LEXIS 47676, at *20. *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 592 (Tex. 1986). Defendant's failure to adequately warn was a breach of its duty and made the energy shot "defective" hence unreasonably dangerous.

One of defendant's main arguments is that Mr. Polanco does not have expert testimony to prove up this legal claim. Mr. Polanco has Dr. Changlani's testimony to

prove up causation. Plaintiff is not required to produce an expert to prove up all of the elements of his legal claims. Causation is key to plaintiff's claims and Dr. Changlani's testimony, the medical records and the treating physicians' testimony are evidence of causation in this case.

A marketing defect occurs when a defendant knows or should know of a potential risk of harm presented by the product but marketed it without *adequately* warning of the danger or providing instructions for safe use. The question for the jury is whether the 5 Hr energy shot has been sold without sufficient (adequate) safeguards and is thereby "unreasonably dangerous as marketed".

A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous. *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006). A 'marketing defect' occurs when a defendant knows or should have known of a potential risk of harm presented by the product but markets it without ***adequately*** warning of the danger or providing instructions for safe use. *DewayneRogers Logging, Inc. v. Propac Industries, Ltd.*, 299 S.W.3d 374 (Tex.App.-Tyler 2009) , reh'g overruled (Dec. 16, 2009).

Where a manufacturer fails to properly warn of the dangerous propensities of a product, the failure to warn may render an otherwise non-defective product unreasonably dangerous. *Munoz v. Gulf Oil Co.*, 732 S.W.2d 62, 65 (Tex.App.-Houston [14th Dist.] 1987). The adequacy of a warning is a question of fact for the jury but the

existence of a duty to warn is a question of law. *Id*.

Where, the product (2 oz bottle) contains an ingredient (200 mg of caffeine) to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, the seller is required to give a warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the *quantity* of the ingredient and the danger. See Restatement (Second) of Torts, Section 402A, Comment j (1965).

Further, where defendant has reason to anticipate that danger may result from a particular use, as where a drug is sold which is **safe only in limited doses**, defendant is required to give adequate warning of the danger (See Comment j, above), and a product sold without such a warning is **in a** defective condition. . See Restatement (Second) of Torts, Section 402A, Comment h (1965). The 5 Hr energy shot, properly prepared, will harm a substantial number of people, therefore the manufacturer defendant should be held liable for the failure to warn people with heart disease, including Mr. Polanco.

Rather, proper warnings here would be addressed to a sizeable group and would be designed to alert each of its members that although the incidence of heart attacks is minute, Mr. Polanco did belong to a substantial class, people with heart disease, which could be unreasonably dangerous because consumption could trigger a heart attack.

In marketing defect cases, a plaintiff must prove that: (1) a risk of harm is inherent in the product or may arise from the intended or reasonable anticipated use of the product; (2) the product supplier actually knew or should have reasonably foreseen

the risk of harm at the time the product was marketed; (3) the product must possess a marketing defect; (4) the absence of a warning or instructions renders the product unreasonably dangerous to the user or consumer of the product; and (5) the existence of a causal nexus between the failure to warn or instruct and the user's injury.

There is no dispute that Mr. Polanco was injured (a heart attack), such should not be in issue. Since the defect alleged, *failure to warn* by the manufacturer, is by definition the manufacturer's dereliction. To find that Mr. Polanco has produced competent evidence that the energy shot caused his injuries, implies that the product is unreasonably dangerous **and** in a defective condition, the two terms are essentially the same.

Danger was foreseeable, as evidence, look at the warning printed on the label. Defendant was obviously aware of the foreseeable danger of its product, due to the language used in the label.

Thus if a product is unreasonably dangerous as marketed, the manufacturer may be held liable for injuries proximately caused by what he has produced, whether or not it was manufactured exactly as intended, that is without a production defect. In this case, the marketing itself amounts to a defect, therefore, all that court needs to determine is whether the energy shot was unreasonably dangerous and whether the showing of proximate causation is sufficient.

Even a product safely designed and manufactured may be unreasonably dangerous as marketed because of a lack of adequate warnings or instructions for safe

use. In this case, defendant already provided a warning and instructions. This case is not about the existence of a duty, but about the adequacy of the warning used & printed within the bottle label. Adequacy of the warning is fact question for the jury

The defendant purposefully left out the amount of caffeine, which now is alleged by them to be 200 mg of caffeine. Since numbers, including the number 200 is both readable and understandable both in English and Spanish, had the defendant printed the number amount of caffeine, then Mr. Polanco would have been able to understand the number 200 next to caffeine. Mr. Polanco would have heeded a warning about the risk of a heart attack had it been printed on the label. Mr. Polanco would have heeded a warning about the risk of 200 mg of caffeine had the number 200 been printed on the label next to the word caffeine. *See attached Exhibit No. 27, Mr. Polanco deposition excerpts and Exhibit No. 28, Mr. Polanco affidavit.* The inadequacies on the label contributed to his injuries and had adequate warning been provided it would have prevented Mr. Polanco from ingesting the product and avoiding the plaque rupture, which led to his heart attack. Mr. Polanco was deposed and during his deposition he was not asked whether or not he would have complied with the warning had the number 200 had been printed next to the caffeine. In fact, had he been asked, Mr. Polanco would have testified that the would have complied with warnings, had the number 200 been printed on the label next to the word caffeine. *See attached Exhibit No. 27, Mr. Polanco deposition excerpts and Exhibit No. 28, Mr. Polanco affidavit.*

Defendant did ask Mr. Polanco if he read the label and why not? Mr. Polanco responded that the label was in English, which he does not understand, but he did state

that he reads his medicine warning labels printed in Spanish. Therefore, whether or not Mr. Polanco would have read the label and follow instructions is another question for the jury. *See attached Exhibit No. 27, Mr. Polanco deposition excerpts and Exhibit No. 28, Mr. Polanco affidavit*

Additionally, since the number 200 is universally understood both in English and Spanish and the word caffeine is spelled quite similar in both English & Spanish: "caffeina," Mr. Polanco would have understood the number 200 being next to the word caffeine, and not consumed the high caffeine beverage. It is the fact that defendant hid the number 200, that caused the actual heart attack suffered by Mr. Polanco, a person who intentionally drinks decaffeinated coffee in a daily basis. Mr. Polanco would not have ingested a high caffeine drink, just like he never consumes other energy drinks nor regular coffee. *See attached Exhibit No. 27, Mr. Polanco deposition excerpts and Exhibit No. 28, Mr. Polanco affidavit.* The omission of an adequate warning of the alleged risks, risk of a heart attack and identifying the amount of caffeine, was the actual cause in fact of Mr. Polanco's heart attack. Whether a warning is adequate is usually a jury question.

-- PREEMPTION

The defendant alleges that since it allegedly complies with 21 C.F.R. Part 340, Stimulant Drug Products for Over-The-Counter Human Use. *See attached Exhibit No. 29, 21 CFR 340.* Defendant's warning does not comply with 21 CFR 340, and therefore, their preemption argument fails. Subpart A, section 340.1 states: " … *and is not misbranded* ***if it meets each of the conditions*** *in this part …"*

The defendant's product fails to comply with section 340.50(a), Statement of Identity, because the product is not labeled as a stimulant. Instead, the product is labeled as a "*Dietary Supplement.*" Further, defendant's product fails to comply with section 340.50(c), Warnings. The defendant was required to state in the label: "*The recommended dose of this product contains about as much caffeine as a cup of coffee.* ***Limit the use of caffeine containing medications, foods or beverages while taking this product*** *because too much caffeine may cause nervousness, irritability, sleeplessness and occasionally, rapid heart beat.*" The label does not include the language in quotations and required by statute. *See attached Exhibit No. 16, shot label.*

The defendant's product also fails to comply with section 340.50(d), Directions. The labeling of the product contains the following information under the heading "Directions": Adults and children 12 years of age and over: **Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours.** This particular section required the defendant to include the number 200 next to the word caffeine. Compliance with this section of the statute, would have prevented Mr. Polanco's injuries. Additionally, the defendant was required to state the amount of milligrams per dose, defendant fails to comply. *See attached Exhibit No. 16, shot label.*

Defendant also appears to be questioning the jurisdiction of the court that they removed the plaintiff into. A plea to the jurisdiction is the proper way to challenge this court's jurisdiction to send this case to an administrative hearing within the FDA. This case presents questions of tort law. His legal claims are well within the court's

jurisdiction and the court should submit this case to a jury and deny defendant's motion for summary judgment in its entirety.

IV. NEGLIGENCE

To recover under a theory of negligence, a plaintiff must show (1) the existence of a duty on the part of one party to another; (2) the breach of that duty; and (3) the injury to the person to whom the duty is owed as a proximate result of the breach. *Rosas v. Buddies Food Store,* 518 S.W.2d 534, 536 (Tex. 1975). Defendant had a legal duty to sell a safe product. Defendant breached that duty when it sold the energy shot because it is unreasonably dangerous for a large group of people with pre-existing and undiagnosed heart disease, like Mr. Polanco.

Mr. Polanco suffered a heart attack as a result of defendant's breach to provide a safe product. By placing the energy shot upon the market, the defendant represented to the public that the energy shot is suitable and safe for use; and by packaging, advertising, and otherwise, defendant did everything it could to induce that belief upon Mr. Polanco. As he testified in response to the shot not being safe: *"I don't think so, Irma. They showed them on the TV and they're not bad." See attached Exhibit No. 30.* Further, to support his negligence claims, *please see all attached exhibits* to this response to motion for summary judgment and *all exhibits attached* to the plaintiff's response to defendant's *motion to exclude Dr. Changlani, hereby incorporated* into this response.

Unless we are going to abandon long-standing public policy grounds for holding manufacturers of defective products responsible for injuries caused by manufactured

products that prove to be defective, Mr. Polanco must be given an opportunity to prove that a malfunctioning energy shot caused his injuries.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on **13th day of March, 2015**, a true and correct copy of Plaintiff's Response to Motion for Summary Judgment has been served on all counsel of record via PACER:

Hon. Jerry Hawxhurst
Hon. Josh Gelbart
Hon. E. Michael Rodriguez

Attorneys for Defendant Innovation Ventures, LLC

Oscar R. Alvarez